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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,534	05/31/2000	BARBARA ENSOLI	11340-003-999	9400
20583	7590	01/09/2008	EXAMINER	
JONES DAY			HUMPHREY, LOUISE WANG ZHIYING	
222 EAST 41ST ST			ART UNIT	
NEW YORK, NY 10017			PAPER NUMBER	
			1648	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/555,534

Applicant(s)

ENSOLI, BARBARA

Examiner

Louise Humphrey, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) 169-178 and 192-198 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 62, 63, 65, 66, 68, 69, 89-103, 105-112, 114, 116, 117, 119, 121-128, 142-168 and 179-191 is/are rejected.
- 7) ☒ Claim(s) 62, 125 and 126 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/24/07</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 62,63,65,66,68,69,89-103,105-112,114,116,117,119,121-128 and 142-198.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 24 October 2007 has been entered.

Claims 1-61, 64, 67, 70-88, 104, 113, 115, 118, 120 and 129-141 have been cancelled. New claims 193-198 have been added and are drawn to a nonelected subject matter and hence are withdrawn from further consideration pursuant to 37 CFR 1.142(b). Claims 62, 63, 65, 66, 68, 69, 89-103, 105-112, 114, 116, 117, 119, 121-128 and 142-198 are pending. Claims 169-178 and 192-198 are withdrawn. Claims 62, 63, 65, 66, 68, 69, 89-103, 105-112, 114, 116, 117, 119, 121-128, 142-168 and 179-191 are currently examined.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Declarations under 37 CFR 1.132

The supplemental Magnani declaration filed on 24 October 2007, the Magnani declaration filed on 01 May 2007, and the Ensoli declaration filed on 01 May 2007 under 37 CFR 1.132 are sufficient to overcome the rejection of claims 62, 63, 65, 66, 68, 69, 89-103, 105-112, 114, 116, 117, 119, 121-123, 127, 128, 142-168, and 179-191 based upon insufficiency of disclosure under 35 U.S.C. §112.

Claim Objections

Claims 62, 125 and 126 are objected to because of the following informalities: the claim limitation "amino acid sequence" does not match SEQ ID NO:7 and SEQ ID NO:9, which are nucleotide sequences. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 62, 63, 65, 66, 68, 69, 89-103, 105-112, 114, 116, 117, 119, 121-123, 127, 128, 142-168, and 179-191 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification commensurate in scope is **withdrawn** upon consideration of the Magnani declaration showing that it is common knowledge in the art to obtain a composition comprising a biologically active Tat that is pharmaceutically acceptable for administration to a human and upon further consideration of the claim limitation "pharmaceutically acceptable for administration to a human" as an intended use limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 62, 63, 65, 66, 68, 69, 89, 90, 93, 94, 106, 107, 128, 142-150, 152, 153, 155-159, 161, 162, 164-168, 179-183, 185, and 186 under 35 U.S.C. §102(b) as being anticipated by Chang *et al.* is **maintained**. Applicant's arguments have been fully considered but are not persuasive.

The instant claims read on a composition comprising an isolated Tat protein in combination with a pharmaceutically acceptable carrier or excipients, wherein said isolated Tat protein is biologically active.

Chang *et al.* teach a composition comprising fully biologically active HIV Tat proteins, which are stored by lyophilization and resuspended in degassed buffer, PBS containing 0.1% BSA and 0.1 mM DTT before use (page 1424, 1st column, Tat protein and anti-Tat antibody, Purification of recombinant Tat protein by heparin affinity chromatography).

Applicant argues that the Chang reference is silent as to whether the resulting Tat composition is pharmaceutically acceptable for administration to a human. However, the “wherein” clause reciting “pharmaceutically acceptable for administration to a human” is not given patentable weight because the intended use does not materially limit the claimed composition to a particular chemical structure that distinguishes over the prior art Tat protein composition. Even Applicant herself admits that this claim limitation is an attribute or characteristic of the claimed composition, and is not a use limitation (see page 16 of the Remark filed on 24 October 2007). Claim scope is not limited by claim language that suggests or makes optional but does not require steps to be performed, or by claim language that does not limit a claim to a particular structure. MPEP §2111.04 [R-3] states: The determination of whether each of these clauses is a limitation in a claim depends on the specific facts of the case. In *Hoffer v. Microsoft Corp.*, 405 F.3d 1326, 1329, 74 USPQ2d 1481, 1483 (Fed. Cir. 2005), the court held that when a “whereby” clause states a condition that is material to

patentability, it cannot be ignored in order to change the substance of the invention.” *Id.* However, the court noted (quoting *Minton v. Nat 'l Ass 'n of Securities Dealers, Inc.*, 336 F.3d 1373, 1381, 67 USPQ2d 1614, 1620 (Fed. Cir. 2003)) that a “whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited.” *Id.*<

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of claims 62, 63, 65, 66, 68, 69, 89, 90, 93-94, 106, 107, 114, 119, 128, 142-150, 152, 153, 155-159, 161, 162, 164-168, 179-183, 185, 186 and 189 under 35 U.S.C. §103(a) as obvious over Chang *et al.* in view of Heiman *et al.* is **maintained**.

Applicant argues that the two purification methods disclosed by Chang *et al.* produce a Tat composition containing HPLC solvents and a protease inhibitor, phenylmethanesulphonylfluoride (PMSF), which are not pharmaceutically acceptable for administration to a human.

Even though there is no explicit suggestion to avoid the use of PMSF in the Chang reference, applicant has admitted on the record that it is commonly known in the art as of December 1st, 1997 that a combination of purification steps should yield

improved purification that decreases levels of endotoxin in the resulting protein preparation and to avoid the use of PMSF in the process in routine experimentation, as evidence by the two Magnani declarations. Therefore, a *prima facie* case of obviousness is properly established.

The rejection of claims 62, 63, 65, 66, 68, 69, 89, 90, 93-95, 97, 101-103, 105-111, 116, 117, 121, 122, 128, 142-168, 179-187, 190, and 191 under 35 U.S.C. §103(a) as obvious over Chang *et al.* in view of Vogel *et al.* is **maintained** for the same reason as set forth above because applicant presented the same arguments as for the rejection as anticipation by Chang *et al.*

The rejection of claims 62, 63, 65, 66, 68, 69, 89, 90, 93-94, 99, 106, 107, 128, 142-150, 152, 153, 155-159, 161, 162, 164-168, 179-183, 185 and 186 under 35 U.S.C. §103(a) as obvious over Chang *et al.* in view of Castignolles *et al.* is **maintained** for the same reason as above.

The rejection of claims 62, 63, 65, 66, 68, 69, 89, 90, 93-94, 100, 106, 107, 128, 142-150, 152, 153, 155-159, 161, 162, 164-168, 179-183, 185 and 186 under 35 U.S.C. §103(a) as obvious over Chang *et al.* in view of Ramshaw *et al.* is **maintained** for the same reason as above.

The rejection of claims 62, 63, 65, 66, 68, 69, 89, 90, 93, 94, 106, 107, 112, 128, 142-150, 152, 153, 155-159, 161, 162, 164-168, 179-183, 185, 186, and 188 under 35 U.S.C. §103(a) as obvious over Chang *et al.* in view of Livingston *et al.* is **maintained** for the same reason as above.

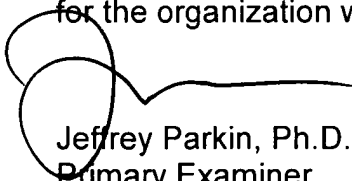
The rejection of claims 62, 63, 65, 66, 68, 69, 89, 90, 93-94, 106, 107, 123, 128, 142-150, 152, 153, 155-159, 161, 162, 164-168, 179-183, 185 and 186 under 35 U.S.C. §103(a) as obvious over Chang *et al.* in view of Barry *et al.* is **maintained** for the same reason as above.

Correspondence

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Jeffrey Parkin, Ph.D.
Primary Examiner
12 December 2007



Louise Humphrey, Ph.D.
Assistant Examiner